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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/888,202    07/07/97    PIMENTEL

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EXAMINER
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HM22/0629

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UNGAR, S

ART UNIT	PAPER NUMBER
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1642

17

DATE MAILED:

06/29/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/888,202

Applicant(s)

Pimentel

Examiner

Ungar

Group Art Unit

1642



☒ Responsive to communication(s) filed on Apr 14, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1, 8, 11, 14, 18, 19, 26-29, 31-33, and 37-39 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1, 8, 11, 14, 18, 19, 26-29, 31-33, and 37-39 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. The Amendment filed April 14, 2000 (Paper No. 15) and the Declaration filed April 14, 2000 (Paper No. 16) in response to the Office Action of October 26, 1999 (Paper No. 13) are acknowledged and have been entered. Previously pending claims 1, 8, 18, 27, 31, 32 and 37 have been amended, claims 2, 3, 17, 20-22, 25, 30 and 34-36 have been canceled and new claims 38 and 39 have been added. Claims 1, 8, 11, 14, 18, 19 and 26-29, 31-33 and 37-39 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 8, 11, 14 and 18-19 remain rejected under 35 USC 103 for the reasons previously set forth in Paper No. 13, Section 5, pages 2-5, Paper No. 8, Section 5, pages 2-3 and Paper No. 5, Section 9, pages 4-8 and claims 26-29, 31-33 remain rejected for the reasons previously set forth in Paper No. 13, Section 5, pages 2-5 and Paper No. 8, Sections 7 and 8, pages 4-7.

Applicant argues that (a) someone skilled in the art at the time the invention was made would find it surprising and unobvious that avian-produced anti-lipase antibodies fed orally to a post-suckling mammal having a normally functioning digestive system would markedly inhibit the pancreatic lipase activity of that mammal. The reasons were set forth previously and in the Atkinson Declaration set forth herein. Applicant then goes on to elaborate on the reasons set forth in the Atkinson Declaration.

In the Atkinson Declaration, Dr. Atkinson argues that (a) he would have been skeptical that lipase antibodies introduced orally into the GI tract of post-newborn

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non-ruminant mammals would have any significant effect in inhibiting pancreatic lipase activity and the teachings of the references, taken in combination would not have led him to a different conclusion, (b) Tetrahydrolipstatin is a molecule that is different than an anti-pancreatic lipase antibody, (c) the secondary references do not make up for the shortcomings of the Hadvary reference since the Moloney, Flint, Ohkaru and Japanese references administer antibodies iv, sc and ip but they are not disclosed as effectively administering antibodies orally, (d) Dr. Atkinson states the opinion that differences in the development of the digestive tracts of nursing offspring lead to differences in processing of ingested antibodies when compared to mature adults and Tokoro and Martin specifically teach administration to sucking animals, (e) Perryman et al and Sterling et al do refer to treatment of adult mammals with orally administered antibodies but these antibodies are directed to different antigens, (f) the Coleman patent is concerned with the treatment of diseases in ruminant animals and not in non-ruminant animals as currently claimed. The arguments have been considered but have not been found persuasive because (a') as previously stated, it was clearly conventional in the art, at the time the invention was made, to orally administer antibodies to animals for intestinal treatments. The stated opinion of Dr. Atkinson, relating specifically to his skepticism that the an anti-lipase antibody would remain active upon oral administration is not persuasive in view of the multiple references presented that specifically demonstrate that orally administered antibodies retain activity in the gastrointestinal tract, (b') as previously stated, the rejection is based on the known efficacy of an anti-lipase activity in combination with the known effects of anti-lipase antibodies and the known efficacy

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of oral administration of antibodies, (c') the Moloney and Flint references were presented, not to support the oral administration of antibodies but rather to demonstrate the state of the art at the time the invention was made, the Ohkaru and Japanese references were presented, not to support the oral administration of antibodies, but rather to demonstrate that anti-pancreatic lipase antibodies which inhibited lipase activity were well known in the art at the time the invention was made (d') Applicant is invited to present objective evidence not only demonstrating that the digestive systems of post-suckling mammals process ingested material in a manner different than suckling mammals but also that all antibody activity is destroyed by the oral ingestion of the antibody, although Tokoro and Martin specifically teach administration to sucking mammals, US Patent No. 5,080,895 specifically suggests the oral administration of antibodies derived from antibodies and does not limit that administration to newborn or suckling mammals.(see column 3), (e') given the teaching of the references one of ordinary skill in the art would expect to successfully deliver functioning antibodies to the GI tract, (f') the argument has been considered and is found persuasive and the Coleman patent, as drawn to administration to non-ruminant animals, is withdrawn.

Applicant further argues that as stated in previous responses the Examiner has used the claimed invention as a blueprint and has not provided motivation for combining the references. The argument has been considered but has not been found persuasive for the reasons previously set forth in Paper No. 8, Section 5. Applicant's arguments have not been found persuasive and the rejection is maintained.

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***New Grounds of Rejection***

***Claim Rejections - 35 USC § 103***

4. Claims 37-39 are rejected under 35 U.S.C. § 103 as being unpatentable over in view of Moloney, of record, Flint, of record, Ohkaru et al, of record or JP 02150294, US Patent No. 5,585,098, US Patent No. 5,080,895 as drawn to the rejection of claims 1- 4, 8, 11, 14 and 17-22.

The claims are drawn to a method of decreasing fat absorption in mammals comprising immunizing a producer animal with pancreatic lipase to produce pancreatic lipase antibody and then orally administering said antibody to inhibit pancreatic lipase.

Moloney, Flint, Ohkaru et al or JP 02150294, US Patent No. 5,585,098, US Patent No. 5,080,895 as drawn to the rejection of claims 1- 4, 8, 11, 14 and 17-22 teach as previously set forth but do not teach a method whereby the antibody is first produced by immunizing a producer animal with pancreatic lipase to produce pancreatic lipase antibody.

It would have been *prima facie* obvious to one of ordinary skill in the art to produce an antibody to be used in the instant method given that US Patent No. 4,598,089 specifically teach that an agent that inhibits pancreatic lipase is useful for treating or preventing obesity, especially in view of the teaching of Ohkaru et al and JP 02130294 that antibodies against pancreatic lipase inhibit lipase activity. One of ordinary skill in the art would have had a reasonable expectation of success in the production of the inhibitory antibodies because Ohkaru et al and JP 02130294

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specifically demonstrate the successful production of antibodies against pancreatic lipase which inhibit lipase activity.

5. All other objections and rejections recited in Paper No. 13 are withdrawn.
6. No claims allowed.
7. Applicant's amendment necessitated the new grounds of rejection.

Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1640.

  
Susan Ungar,  
Primary Patent Examiner  
June 20, 2000